

Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the materials, parts, and components of the packaging.

(b) The licensee shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee shall apply design control measures to items such as the following:

- (1) Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses;
- (2) Compatibility of materials;
- (3) Accessibility for inservice inspection, maintenance, and repair;
- (4) Features to facilitate decontamination; and
- (5) Delineation of acceptance criteria for inspections and tests.

(c) The licensee shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the package approval require NRC approval.

§71.109 Procurement document control.

The licensee shall establish measures to assure that adequate quality is re-

quired in the documents for procurement of material, equipment, and services, whether purchased by the licensee or by its contractors or subcontractors. To the extent necessary, the licensee shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this part.

§71.111 Instructions, procedures, and drawings.

The licensee shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

§71.113 Document control.

The licensee shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must assure that changes to documents are reviewed and approved.

§71.115 Control of purchased material, equipment, and services.

(a) The licensee shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.

(b) The licensee shall have available documentary evidence that material